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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,013	10/09/1998	TIMOTHY H. BESTOR	48075-B-PCT	7512

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/03/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/051,013

Applicant(s)

BESTOR, TIMOTHY H.

Examiner

David J. Steadman

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 September 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 1,4,6-12,15,16,24-26 and 42-46.Claim(s) withdrawn from consideration: 2,3,5,13,14,17-23,29,34-41 and 47.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other:

Continuation of 3. Applicant's reply has overcome the following rejection(s): 112, 2nd paragraph rejection of claims 1 and 6.

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**ADVISORY ACTION**

***Application Status***

Claims 1-26, 29, and 34-47 are pending in the application.

Cancellation of claims 27, 28, and 30-33 and amendment of claims 1, 6, 11, 12, 15, and 24 in Paper No. 11, filed 09/28/01 is acknowledged.

Claims 2, 3, 5, 13, 14, 17-23, 29, 34-41, and 47 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claims 1, 4, 6-12, 15, 16, 24-26, and 42-46 are being examined on the merits to the extent the claims read on the elected species.

The request for reconsideration has been considered but does not place the case in condition for allowance for the reasons discussed below.

***Advisory***

1. The written description rejection of claims 1, 4, 6-10 and 42-46 under 35 USC 112, first paragraph is maintained. Applicants argue that the instant specification in combination with the state of the art is fully enabling for the skilled artisan to make and use applicants' claimed chimeric polypeptides. Applicants argue that specific examples of a chimeric polypeptide that inhibits expression of a gene associated with cancer or AIDS, a chimeric polypeptide that specifically targets a promoter of an endogenous gene associated with cancer, or polynucleotide sequences that encode the claimed chimeric polypeptides need not be provided as the specification, in combination with the prior art provides sufficient guidance to generate the claimed chimeric polypeptides and encoding polynucleotides. Applicants' arguments are not found persuasive for the reasons of record. It is noted by the examiner that much of applicants' arguments are applicable to the issue of enablement and *not* the instant issue of sufficient written description. Furthermore, the rejection is based on the lack of written description of

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applicants' claimed chimeric protein comprising a DNA methyltransferase and a DNA binding protein and not the promoter to which the DNA binds.


2. The enablement rejection of claims 1, 4, 6-12, 15, 16, 24-26, and 42-46 under 35 USC 112, first paragraph is maintained. Applicants states that the instant specification teaches successful methylation and inhibition of HIV-1 replication in HIV-1 infected T-lymphocytes, successful inhibition of HIV-1 LTR-dependent transcription HL2/3 cells, identification of CpG methylation sites, and design, selection, and affinity maturation of methyltransferase chimeric polypeptides that methylate critical CpG sites in the HIV 5'-LTR. Applicants extensively argue that the information provided in the instant specification is sufficient to enable a skilled artisan to make and use the claimed chimeric polypeptides. Applicants further argue that all mammalian promoters characterized to date are silenced upon methylation of cytosine at CpG sites and that the examiner has provided no evidence that the involvement of DNA methylation to carcinogenesis is an hypothesis and remains to be tested. Applicants' arguments are not found persuasive for the reasons of record.

3. In view of applicants' amendment to claims 1 and 6 to replace the term "with attenuated DNA binding activity" with "whose DNA binding activity is attenuated relative to that of naturally occurring DNA methyltransferase", rejection of claims 1, 4, 6-10, 15, 16, 24-26, and 42-46 under 35 USC 112, second paragraph is withdrawn.

4. No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 6:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

  
**REBECCA E. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
*RPD*